K131208

510(k) SUMMARY

Submitter Information:

SEP 11 2013

Date Prepared:	August 14, 2013
Name:	Bausch & Lomb Incorporated
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Device Information:

Trade Name:

Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens

Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism

Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia

Common Name: Soft contact lens, daily wear

Device Classification: Class II (21 CFR 886.5925)

Classification Name: Daily Wear Soft (Hydrophilic) Contact Lens

Product Code: LPL, MVN

Predicate Device:

The predicate device is the

- Bausch + Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens cleared under K122575,
- Bausch + Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens cleared under K122575,
- Bausch + Lomb PureVision Multi-Focal (balafilcon A) Visibility Tinted Contact Lens cleared under K050948.

Device Description:

The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens, Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is 46% water and 54% samfilcon A material (a siloxane copolymer with N-vinyl pyrrolidone). This lens is tinted blue with Reactive Blue Dye 246 to make them easier to see when handling.

The packaging material consists of a polypropylene blister, borate buffered saline with poloxamine and a plastic coated aluminium lid stock. The disposable blister container and the lidstock are used in the predicate device. The packaged lenses are steam sterilized in a validated autoclave. Each lens is labelled with the lens parameters, lot number and expiration date.

Lenses have the following physical properties:

Refractive Index:	1.411
Light Transmittance:	97.3%
Water Content:	46%
Specific Gravity:	1.048
Oxygen Permeability:	114 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)

The lens designs include spherical, toric and multifocal lenses in the following parameter ranges:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm (varies with power)
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D
Cylinder Power (Toric)	-0.75D to -5.00D
Cylinder Axis (Toric)	0^0 to 180^0
Add Power (Multi-Focal)	+0.75D to +5.00D

Indications for Use:

The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D
to –20.00D.

The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to –20.00D.

The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens, Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens, Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be discarded after each removal.

Technological Characteristics:

The table below shows a side-by-side comparison of technological characteristics evaluated to determine substantial equivalence of the new device to the predicate device. Differences were evaluated during the design and development of the new device. Performance testing was completed and demonstrated the proposed device and predicate device are substantially equivalent and the differences do not negatively impact the safety and efficacy of the device.

Property	**Predicate Device(s)** Bausch +Lomb PureVision (balafilcon A) Product Family *K050948 and K122575*	**New Device** Bausch + Lomb (samfilcon A) Product Family
Intended Use	Daily Wear, Daily Disposable	Same
Lens Material Group	Silicone Hydrogel	Same
Visibility Tint	Reactive Blue 246	Same
Manufacturing Method	Cast Molded	Same
Lens Designs	Spherical, Toric, Multifocal	Same
Sterilization Method	Autoclave	Same
Packaging	Polypropylene Blister	Same
Packaging Solution	Borate Buffered Saline	Borate buffered saline with Poloxamine
USAN Name	balafilcon A	samfilcon A
Water Content	36%	46%

Summary of Non-Clinical Testing:

Non-clinical testing was conducted to verify substantial equivalence of the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens to the predicate, Bausch & Lomb PureVision (balafilcon A) Contact Lens. Non-clinical biocompatibility was conducted in accordance with FDA's *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses,* May 1994 and GLP regulation (21 CFR part 58).

Non-clinical testing performed includes:

- physiochemical per ISO 18369-4,
- biocompatibility per ISO 10993-5, ISO 10993-10 and ISO 10993-11,
- ocular irritation per ISO 9394,

- stability per ISO 11987,
- preservative uptake per ISO 11986,
- extractables per ISO 18369-4 and
- solution compatibility ISO 11981.

All test results met the pre-established acceptance criteria.

The testing performed on the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens demonstrates the lens is safe and effective. Non-clinical testing included conformance to predetermined specifications. All test results verify that the device performs as expected and is substantially equivalent to the predicate device without adversely impacting safety and efficacy.

Summary of Clinical Performance Data:

A prospective, three-month randomized clinical study utilizing adopted soft contact lens wearers was conducted. This study evaluated the safety and effectiveness of the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens. In addition, the study was performed to establish substantial equivalence to the predicate device, Bausch & Lomb PureVision (balafilcon A) Contact Lens.

The primary safety variable was biomicroscopy findings and the primary efficacy variable was visual acuity. Additional variables were tested, including refraction, keratometry and ratings of vision, comfort, and handling and "other" symptoms.

The primary safety and efficacy endpoints were achieved and no adverse events occurred during the study.

In conclusion, the results of the study demonstrated that the lens is safe and effective and is substantially equivalent to the predicate device.

Risks and Benefits:

The risks of the subject device are the same as those found in the predicate device. The benefits to the patient are the same as those in the predicate device and outweigh the risks when worn according to instructions.

Substantial Equivalence Conclusion:

The cumulative results of the non-clinical and clinical testing sponsored by Bausch + Lomb demonstrate that the safety, efficacy and performance of Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens are substantially equivalent to the predicate lenses and similar to other daily wear soft contact lenses on the market.

Any differences that may exist between the samfilcon A contact lens and other silicone hydrogels do not adversely affect the safety and efficacy of the Bausch + Lomb (samfilcon A) Contact Lens when worn according to instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 11, 2013

Bausch + Lomb
% Ms. Barbara Klube-Falso
Sr. Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K131208
Trade/Device Name: Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens,
Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism,
Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 15, 2013
Received: August 19, 2013

Dear Ms. Klube-Falso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131208

Device Name: Bausch + Lomb samfilcon A Soft (hydrophilic) Contact Lens; Bausch + Lomb samfilcon A Soft (hydrophilic) Contact Lens for Astigmatism; Bausch + Lomb samfilcon A Soft (hydrophilic) Contact Lens for Presbyopia.

Indications For Use:
The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to –20.00D.

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FREQUENT/PLANNED REPLACEMENT WEAR
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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Marc W. Robboy -S

Digitally signed by Marc W. Robboy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Marc W. Robboy -S, 0.9.2342.19200300.100.1.1=1300392796
Date: 2013.09.17 12:31:15 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number **K131208**